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| APPLICATION NO.                       | FILING DATE     | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------------------|-----------------|----------------------|---------------------|------------------|
| 09/943,458                            | 08/30/2001      | Dwight D. Weller     | 50450-8038.US00     | 9454             |
| 22918                                 | 7590 07/15/2005 |                      | EXAM                | INER             |
| PERKINS COIE LLP                      |                 |                      | KIM, YOUNG J        |                  |
| P.O. BOX 2168<br>MENLO PARK, CA 94026 |                 |                      | ART UNIT            | PAPER NUMBER     |
|                                       | •               |                      | 1637                | <u> </u>         |

DATE MAILED: 07/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| ·   | and a   |   |  |  |  |  |
|---|---|---|--|--|--|--|
|   | Application No.   | Applicant(s)  |  |  |  |  |
|   | 09/943,458  | WELLER ET AL.   |  |  |  |  |
| Office Action Summary   | Examiner  | Art Unit  |  |  |  |  |
|   | Young J. Kim  | 1637  |  |  |  |  |
| The MAILING DATE of this communication a<br>Period for Reply  | ppears on the cover sheet w   | vith the correspondence address   |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REF THE MAILING DATE OF THIS COMMUNICATION  - Extensions of time may be available under the provisions of 37 CFR after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a re- If NO period for reply is specified above, the maximum statutory perions  - Failure to reply within the set or extended period for reply will, by state Any reply received by the Office later than three months after the mail earned patent term adjustment. See 37 CFR 1.704(b). | N. 1.136(a). In no event, however, may a eply within the statutory minimum of thing will apply and will expire SIX (6) MO tute, cause the application to become A | reply be timely filed  rty (30) days will be considered timely.  NTHS from the mailing date of this communication.  BANDONED (35 U.S.C. § 133). |  |  |  |  |
| Status  |   |   |  |  |  |  |
| 1)⊠ Responsive to communication(s) filed on 05  | May 2005.   |   |  |  |  |  |
| <u>~=</u> · · · · <u>-</u>  |   |   |  |  |  |  |
| 3) Since this application is in condition for allow   | ) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is   |   |  |  |  |  |
| closed in accordance with the practice under  | closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.   |   |  |  |  |  |
| Disposition of Claims   |   |   |  |  |  |  |
| 4)⊠ Claim(s) <u>1-11,15-17 and 19-27</u> is/are pendin  | g in the application.   |   |  |  |  |  |
|   | 4a) Of the above claim(s) is/are withdrawn from consideration.  |   |  |  |  |  |
| 5) Claim(s) is/are allowed.   |   |   |  |  |  |  |
| 6) Claim(s) <u>1-10,15,19-24,26 and 27</u> is/are reje  | 6)⊠ Claim(s) <u>1-10,15,19-24,26 and 27</u> is/are rejected.  |   |  |  |  |  |
| 7) Claim(s) 11,16,17 and 25 is/are objected to.   |   |   |  |  |  |  |
| 8) Claim(s) are subject to restriction and  | l/or election requirement.  |   |  |  |  |  |
| Application Papers  |   |   |  |  |  |  |
| 9)☐ The specification is objected to by the Exami   | ner.  |   |  |  |  |  |
| 10)⊠ The drawing(s) filed on 30 August 2001 is/are  | e: a)⊠ accepted or b)□ o  | bjected to by the Examiner.   |  |  |  |  |
| Applicant may not request that any objection to the   | ne drawing(s) be held in abeya  | nce. See 37 CFR 1.85(a).  |  |  |  |  |
| Replacement drawing sheet(s) including the corre  | ection is required if the drawing   | g(s) is objected to. See 37 CFR 1.121(d).   |  |  |  |  |
| 11) The oath or declaration is objected to by the   | Examiner. Note the attache  | d Office Action or form PTO-152.  |  |  |  |  |
| Priority under 35 U.S.C. § 119  | ·   |   |  |  |  |  |
| 12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:  1. Certified copies of the priority docume  |   | § 119(a)-(d) or (f).  |  |  |  |  |
| 2. Certified copies of the priority docume  |   | Application No  |  |  |  |  |
| Copies of the certified copies of the prapplication from the International Bure   | iority documents have beer  | <del></del>   |  |  |  |  |
| * See the attached detailed Office action for a lie   | ,   | received  |  |  |  |  |
|   | or or the document depressing   |   |  |  |  |  |
|   |   |   |  |  |  |  |
| Attachment(s)   |   | . 62  |  |  |  |  |
| 1) Notice of References Cited (PTO-892)   |   | Summary (PTO-413)   |  |  |  |  |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  Paper No(s)/Mail Date  Notice of Informal Patent Application (PTO-152)   |   |   |  |  |  |  |
| Paper No(s)/Mail Date   | 6) Other:   |   |  |  |  |  |

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## **DETAILED ACTION**

#### Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 5, 2005 has been entered.

## Preliminary Remark

Claims 1-11, 15-17, and 19-27 are pending and are under prosecution.

# Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 4, 7-9 and 20-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites the phrase, "the nucleotide sequence of each analyte," but there is no antecedent basis that the analyte is a nucleic acid in the parent claim.

Claim 4 is indefinite for reciting the phrase, "the *probe* has a length and a sequence such that its duplexes with different analyte molecules differ with respect to the presence, length or position of an unhybridized portion of *the nucleic acid*," because it is unclear what is being

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referred to by the phrase, "the nucleic acid." For the purpose of purpose of prosecution, the phrase, "nucleic acid," is assumed to mean, "the probe."

Claims 7-9 recites the term, "N-1," without defining what "N" is, resulting in the indefinite metes and bounds of the probe which includes a sequence complementary to an N-1 deletion variant. For the purpose of prosecution, "N" has been interpreted to mean the entire length of an oligomeric analyte molecule.

Claim 20 is indefinite for reciting the phrase, "and chimeras of any member of this group with another member," because it is unclear where the "another member" is from.

For the purpose of prosecution, "another member" is also interpreted to be from the preceding Markush group.

Claims 21 and 22 are indefinite by way of their dependency on claim 20.

## Claim Rejections - 35 USC § 102

The rejection of claims 1-11, 16, 17, 19, 20, and 23-27 under 35 U.S.C. 102(b) as being anticipated by Cummins et al. (U.S. Patent No. 5,874, 213, issued February 23, 1999), made in the Office Action mailed on January 5, 2005, is withdrawn in view of the Amendment received on May 5, 2005.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1-6, 10, 15, 19, 20, 23-24, and 26-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Celebuski (U.S. Patent No. 5,932,413, issued August 3, 1999).

Celebuski discloses a method of separating a population of duplexes, each comprising one of a population of different oligomeric analyte molecules hybridized with a specific probe molecule, said method comprising the steps:

- a) applying to a charge-bearing separation medium (a separation column) (column 1, lines 57-58; column 6, lines 35-54) a mixture of:
  - i) DNA molecules (M13mp18) (column 1, lines 53-55; column 6, lines 35-38) which is inherently negatively charged; and
  - ii) an oligonucleotide which is uncharged or substantially uncharged (or substantially neutral) (column 2, lines 60-67); and
- b) separating the duplex formed between the DNA molecule and the oligonucleotide molecule (column 1, lines 60-66; column 2, lines 31-34).

The method involves the use of an unspecified moles of oligonucleotide (thus a plurality of uncharged molecule) and DNA molecule, forming a mixture of species of "probe-analyte duplexes."

The term, "probe-analyte duplexes" does not exclude the duplexes formed between a single type of probe and a plurality of the same analytes. In the instant case, the plurality of uncharged oligonucleotides of Celebuski et al. hybridizes with the same DNA molecule (M13mp18), producing multiple uncharged oligonucleotide:DNA duplexes.

The term, "analyte" and "probe" are arbitrary, so long as the limitations of the claims are met.

With regard to claims 3 and 10, while claims 3 and 10 further define one of the members of recited in the Markush group of claim 2, does *not* require that nucleotide sequence of each analyte actually be internal deletion, insertion, or mutation per 8 nucleotides (claim 3) nor have sequence variations.

With regard to claims 26 and 27, the eluted duplexes are assayed for and quantified (column 2, lines 39-44).

Therefore, Celebuski anticipates the invention as claimed.

# Claim Rejections - 35 USC § 103

The rejection of claim 15 as being unpatentable over Cummins et al., (U.S. Patent No. 5,874,213, issued February 23, 1999) in view of Ness et al. (U.S. Patent No. 6,613,508 B1, issued September 2, 2003, filed July 22, 1997), made in the Office Action mailed on January 5, 2005, is withdrawn in view if the Amendment received on May 5, 2005.

The rejection of claims 21 and 22 under 35 U.S.C. 103(a) as being unpatentable over Cummins et al. (U.S. Patent No. 5,874,213, issued February 23, 1999) in view of Valdivia et al. (WO 96/36734, November 21, 1996), made in the Office Action mailed on January 5, 2005, is withdrawn in view if the Amendment received on May 5, 2005.

# Conclusion

No claims are allowed.

## Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The

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Examiner is on flex-time schedule and can best be reached from 8:30 a.m. to 4:30 p.m. The Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

If attempts to reach the Examiner by telephone are unsuccessful, the Primary Examiner in charge of the prosecution, Dr. Kenneth Horlick, can be reached at (571) 272-0784. If the attempts to reach the above Examiners are unsuccessful, the Examiner's supervisor, Dr. Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Young J. Kim Patent Examiner

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YOUNG J. KIM
PATENT EXAMINER